UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TINA WORLEY, ***Plaintiff,***	**Case No.** 1:25-cv-10592
V. **HOLOGIC, INC.,** ***Defendant.***	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, Tina Worley ("Plaintiff"), brings this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

VENUE AND JURISDICTION

Venue is proper in this Court pursuant to 28 U.S.C. §§ 101, 1391, 1441(a), because (1) Defendant resides in this judicial district; and (2) a substantial part of the events or omissions giving rise to the claim occurred in this district. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because (1) there is complete diversity of citizenship between Plaintiff and Defendant; and (2) the amount in controversy exceeds $75,000, exclusive of interests and costs.

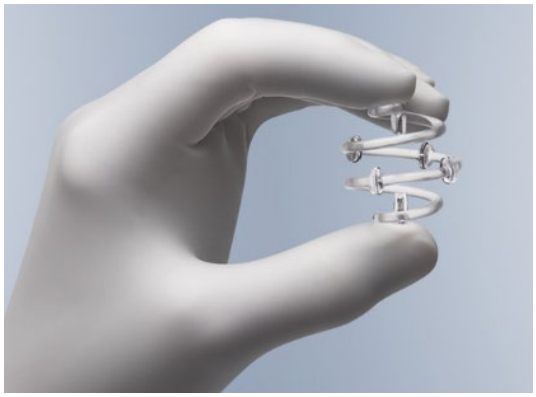
INTRODUCTION

1. Plaintiff, a breast cancer survivor, was implanted with a device called BioZorb ("BioZorb" or "BioZorb Marker") that was manufactured by Hologic.

2. BioZorb is an implantable medical device. It is a unique three-dimensional radiographic bioabsorbable marker used to mark soft tissue sites. The most common use of the

BioZorb is to mark radiation therapy site(s) in a patient's breast following breast cancer lumpectomy, which is how the device was used in Plaintiff's case.

3. The bulk of BioZorb device, which is the circular or spiral component (pictured below) is bioabsorbable compound made primarily of polylactic acid. The device is embedded with six (6) titanium radiopaque marker clips that serve as "targets" for radiation therapy. The bioabsorbable spacer material is supposed to be resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site.



4. This lawsuit is a personal injury action against Defendant Hologic who is responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling of the BioZorb.

PARTIES

Plaintiff

5. Plaintiff is, and at all relevant times was, a citizen and resident of the State of Tennessee and the United States and over the age of eighteen (18) years.

6. Plaintiff was diagnosed with breast cancer in or around 2019. She underwent a partial lumpectomy of her right breast on March 6, 2019, at Ascension Saint Thomas Hospital West in Nashville, Tennessee, during which a BioZorb device was properly implanted by Dr. Lisa S. Bellin, MD.

7. Plaintiff suffered from injuries at and around the site of the BioZorb device. Plaintiff experienced pain and swelling at the site of the BioZorb device.

8. As a result of the BioZorb implant, Plaintiff has been caused to have significant pain, disfigurement, and worry, leaving her permanently and physically scarred. Plaintiff's complications, disfigurement, and non-absorption are not warned of on the Instructions for Use but were risks Defendant knew, or should have known, and failed to disclose to physicians and patients.

Defendant

9. Defendant Hologic is headquartered in Marlborough, Massachusetts which was, and is, engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, the BioZorb device. Hologic is registered to do business in, and routinely does business through employees, contractors, and agents, and enjoys protection of the laws of both Massachusetts and Arkansas.

10. The BioZorb device is a class II medical device first cleared by the FDA in 2012. BioZorb is a tissue marker and is an implantable device developed to mark the surgical site of tissue removal in three dimensions. It has six (6) titanium marker clips distributed in a three-dimension (3D) pattern inside a bioabsorbable polylactic acid (PLA) coil, in either a helical or low profile (LP) flat, oval option, that is intended to facilitate the identification and delivery of more focused radiation therapy.

BACKGROUND AND FACTS

A. Background on BioZorb

11. The BioZorb is a Class II medical device cleared by the United States Food and Drug Administration ("FDA") in February 2012 pursuant to Section 510(k) of the Food and Drug, and Cosmetic Act ("510(k)).

12. BiZorb is a three-dimensional implantable radiographic marker. It is comprised of a bioabsorbable spacer that holds six radiopaque titanium clips. The bioabsorbable spacer material (polylactic acid) is intended to be resorbed in the body by hydrolysis, leaving the radiopaque clips as permanent indicators of the soft tissue site.

13. BioZorb is indicated for use in radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. It may be used with the following imaging modalities: X-ray (CT and mammography), MRI, and ultrasound.

14. BioZorb's Instructions for Use ("IFU") (including all accompanying warnings), of which the same or substantially same applied to Plaintiff at the time of her implant, are illustrated below:

BioZorb® Marker, BioZorb® LP Marker
Instructions for Use

DESCRIPTION

The Marker is a radiographic implantable marker used to mark soft tissue.
It is comprised of a bioabsorbable spacer that holds Titanium radiopaque marker clips. The bioabsorbable spacer material (poly lactic acid) is resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site.
The Marker may be used with the following imaging modalities: X-Ray (CT, mammography), MR and ultrasound.
The bioabsorbable spacer is resorbed by a process of hydrolysis whereby the degradation products of the spacer material are metabolized by the body. The spacer material retains its functional integrity for approximately 2 months, while complete resorption may require up to one or more years.

INDICATIONS

The Marker is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

CONTRAINDICATIONS

The Marker should not be placed in a tissue site with clinical evidence of infection.

WARNINGS

- The Marker should only be used by physicians trained in surgical techniques. The physician is responsible for its proper clinical use.
- The Marker is shipped sterile; do **NOT** re-sterilize any portion of the Marker.
- The Marker is for **SINGLE USE** only.
- Do **NOT** use if the package is open or damaged, or if the temperature indicator has a black center.
- Use the Marker prior to the expiry date shown on the product label.

PLACEMENT OF MARKER

PREPARATION

1) Remove the Marker from the sterile packaging.
2) Visually inspect the product for any damage.

INSERTION

1) Using sterile technique, place the Marker in the desired tissue site.
2) Suture the marker to adjacent tissue at multiple locations as desired for secure positioning.
3) Where required, close the surgical cavity using standard surgical technique.

DISPOSAL PROCEDURES

When necessary, dispose of any product in accordance with local regulations.

STORAGE

Store at room temperature. Avoid storing the Marker at conditions of excessive heat or humidity. If the temperature indicator has a black center, do not use product. Handle with care. Packages should be stored in a manner that protects the integrity of the package and the sterile barrier.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the BioZorb® Marker / BioZorb® LP Marker is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 T; Maximum spatial field gradient of 1,900 gauss/cm (19 T/m); Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode); 15 minutes of continuous scanning

Under the scan conditions defined above in non-clinical testing, the Marker was shown to produce a maximum temperature rise of less than 1.6°C. In addition, the image artifact caused by the marker clip of the device extended an average of 3.8mm from the Marker when imaged with a gradient echo and spin echo pulse sequence and a 1.5T MRI system. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

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15. The FDA rejected clearing BioZorb for the indication that it provides a reference from which treatment (e.g. radiotherapy) can be guided.

16. Defendant marketed BioZorb as a device that can fill space in breast tissue, improve cosmetic outcomes after procedures, and guide radiotherapy. The FDA did not clear any of these indications for use.

B. The Problems with BioZorb and the Inadequacy of the Instructions for Use

17. The IFU for BioZorb contains no warnings or contraindications of any substance to effectively warn patients, physicians, or hospitals of the relevant risks associated with the use of the device.

18. The BioZorb IFU and Defendant's marketing of the BioZorb indicate the device is intended to completely resorb in up to one or more years. However, there is evidence that the device can take significantly longer than one year to absorb, or it may fail to absorb at all. These risks are not mentioned in the IFU.

19. Hologic was aware of Medical Device Reports ("MDRs") that reported patient complications including, but not limited to, infection, fluid buildup, device migration, device erosion, pain, discomfort, rash, extended resorption time of the device, and additional surgeries. These risks are not mentioned in BioZorb's IFU.

20. Hologic also knew, or should have known, of clinical evidence that BioZorb can cause a hard, palpable lump causing patient pain and discomfort. These risks are not mentioned in BioZorb's IFU.

21. Hologic also knew, or should have known, of clinical evidence that shows that BioZorb may increase a patient's radiation dose, contributing to further complications. As one breast surgery noted, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low energy

electrons such as 6 MeV or 9MeV. Such energies give modest doses to the skin and leave no permanent scarring. As you increase in energy electrons, it increases the skin dose and you run the risk of seeing more early and late skin reactions. The most disfiguring side effect [of using the BioZorb device] is the appearance of telangiectasias, which look like red spider veins. These risks are not mentioned in BioZorb's IFU.

22. Hologic also knew, or should have known, of clinical evidence that the device was causing infection, migration, necrosis, additional radiation, and additional surgery. These risks are not mentioned in BioZorb's IFU.

C. FDA Issues a Safety Communication Regarding Potential Risks of Using BioZorb Markers in Breast Tissue.

23. On February 27, 2024, the U.S. Food and Drug Administration issued a Safety Communication ("February 27 Notice") regarding BioZorb Markers.

24. The February 27 Notice informed patients, healthcare providers, and hospitals about the potential risk of serious complications when using BioZorb Markers manufactured by Hologic.

25. The FDA issued the February 27 Notice after receiving reports describing complications (adverse events) with the use of BioZorb Markers in breast tissue including infection, fluid buildup (seroma), device moving out of position (migration), device breaking through the skin (erosion), pain, discomfort from feeling the device in the breast, rash, other complications "possibly associated with" extended resorption time (resorbable component of the device not resorbing in the patient's body for several years), and the need for additional medical treatment to remove the device.

26. The FDA noted in the February 27 Notice that it had cleared BioZorb Markers for radiographic marking of sites in soft tissue (including breast) or for marking the soft tissue site for future medical procedures.

27. In the February 27 Notice, the FDA stated that it had not cleared or approved the BioZorb Markers to fill space in the tissue or to improve cosmetic outcomes after procedures.

28. From its entry into the market, Defendant marketed and promoted the BioZorb Markers to hospitals and surgeons as a device that fills space in breast tissue and improves cosmetic outcomes following surgery.

29. Surgeons relied on the Defendant's representations and implanted BioZorb Markers in patient, including Plaintiff.

30. Hospitals relied on Defendant's representations and allowed use of BioZorb Markers in patients, including Plaintiff.

31. The FDA noted that Defendant had not provided any data to support its claim that the device improved cosmetic outcomes.

D. FDA Class I Recall of BioZorb Marker.

32. On March 13, 2024, pursuant to FDA direction, Hologic sent an Important Medical Device Safety Notification ("Safety Notification") to affected customers.

33. The Safety Notification was to request that patients contact their healthcare provider if they experience any adverse events following the placement of a BioZorb Marker; report any problems or complications experienced following the placement of the BioZorb Marker devices to Hologic and to the FDA's MedWatch Adverse Event Reporting program; and discuss the benefits and possible risks of implantable breast tissue markers for breast cancer procedures with their health care provider.

34. The Important Medical Device Safety Notification was also required to be sent to healthcare providers, and Hologic requested that the healthcare providers be aware of serious adverse events following possible risks of BioZorb Marker devices with each patient; inform all patients on which device will be used if a marking device will be used during breast conservation surgery; continue to monitor patients who have an implanted BioZorb Marker for signs of any adverse events; and report any problems or complications experienced by patients following placement of the BioZorb Marker devices to Hologic and the FDA's MedWatch Adverse Event Reporting program.

35. On May 22, 2024, the FDA classified Hologic's communications to its customers as a Class I recall.

36. Class I recalls are the most serious type of recall.

37. The FDA further noted that the use of BioZorb Markers may cause serious injuries or death.

38. The FDA indicated that this recall was a correction, not a product removal.

39. Complaints that led to the recall included reports of pain, infection, rash, device migration, device erosion, seroma, discomfort, or other complications from feeling the device in the breast, and the need for additional medical treatment to remove the device.

E. December 2024 FDA Warning Letter to Hologic.

40. The FDA inspected Hologic's Marlborough, Massachusetts facility on July 30, 2024 through September 24, 2024.

41. On December 18, 2024, the FDA sent a Warning Letter to Hologic, stating that the inspection revealed the BioZorb devices "are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their

manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

42. In the Warning Letter, the FDA noted violations, including, but not limited to, the following:

a. "[Hologic] failed to establish design inputs to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c);"

b. "[Hologic] failed to verify your device design to confirm that the design output meets the design input requirements, as required by 21CFR 820.30(f);"

c. "[Hologic] failed to validate your device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g);"

d. "[Hologic] failed to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h);"

e. "[Hologic's] review of quality data was not sufficient to detect recurring problems;"

f. "[Hologic] did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports;"

g. "[Hologic's] BioZorb Marker is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2);" and

h. The FDA found that their inspection "revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing,

storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

43. The FDA also noted that the Warning Letter "is not intended to be an all-inclusive list of the violations at [Hologic's] facility,"

CAUSES OF ACTION

COUNT I: STRICT LIABILITY – DESIGN DEFECT

44. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

45. At all relevant times, Defendant, directly or indirectly, designed, researched, developed, inspected, tested, assembled, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers.

46. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiff.

47. The BioZorb Marker was expected to and did reach Plaintiff without substantial change in the condition which it was sold.

48. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiff, when they left Defendant's control.

49. At the time BioZorb Markers left Defendant's control, the foreseeable risks associated with its design exceeded the benefits because of its design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts.

50. The design aspects of the BioZorb could have been feasibly changed to make the device less harmful and not unreasonably dangerous.

51. In the oncological surgical market, practicable alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb.

52. The technologically feasible and practicable alternative designs would have reduced or prevented Plaintiff's harm.

53. For example, titanium clips that have been on the market for years carry less clinical risk to the patient. In fact, at least one clinical study has found that the use of clips to mark a cancer patient's tumor bed is more cost effective and advantageous than the use of BioZorb.

54. BioZorb's design poses a high gravity of danger, beyond that of the reasonable consumer's contemplation.

55. The risks of the design of the BioZorb device outweigh the benefits of its design aspects. The material of the BioZorb spacer makes the device defective because it is intended to absorb; however, it either does not absorb or, as it does, the device fractures into pieces that can migrate throughout the breast and even protrude through a patient's skin. A different material with faster absorption and less crystallinity would help the device degrade in a melting fashion, instead of by fracturing, and would reduce the risks of palpability, pain, hard lumps, protrusion, and surgical removal of the device.

56. The BioZorb poses an unreasonable risk of migration, infection, chronic seroma and/or fluid buildup, chronic pain, and/or the device becomes a chronic "mass" that must be surgically removed. The thickness of BioZorb's spacer could have been reduced to improve the device's degradation time, thus reducing the risks of palpability, pain, hard lumps, and surgical removal of the device.

57. The BioZorb is defective because of its design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts.

58. The defects in the design of BioZorb resulted from the Defendant's action and/or inaction.

59. Defendant knew or should have known that BioZorb Markers presented an unreasonable risk to patients implanted with the device when put to its intended and reasonably anticipated use.

60. The health risks associated with BioZorb Markers, as described herein, are of such a nature that ordinary customers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

61. Defendant did not take reasonable precautions in an attempt to design a safe product and did not act as a reasonably prudent manufacturer would have under the circumstances. For example, Defendant knew its design of BioZorb was defective and that it was feasible to design the device in a safer manner, yet failed to take any action to correct the design and/or to warn patients, physicians, and hospitals of the risks posed by the design.

62. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

63. Defendant failed to establish design inputs for BioZorb to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c).

64. Defendant failed to verify BioZorb's device design to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f).

65. Defendant failed to validate BioZorb's device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g).

66. Defendant failed to ensure that the BioZorb device design was correctly translated into production specifications, as required by 21 CFR 820.30(h).

67. Defendant failed to identify the following for BioZorb Markers: the intended patient population, intended anatomy types, and surgical requirements, such as the appropriate placement and fixation of the device, and the appropriate depth of the implant into the soft tissue.

68. Hologic violated applicable state laws by manufacturing, marketing, selling, and distributing its defectively designed BioZorb Marker.

69. The design of the BioZorb Marker was a substantial factor in causing the resulting harm to Plaintiff.

70. Plaintiff was harmed due to the defective design of the BioZorb Marker.

71. WHEREFORE, Plaintiff demands judgement against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II: STRICT LIABILITY – FAILURE TO WARN

72. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

73. At all relevant times, Defendant, directly or indirectly, designed, researched, developed, inspected, tested, assembled, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers.

74. Defendant had a duty to produce a product that contained adequate warnings and had a duty to disclose the dangers and risks of the BioZorb device, which Defendant knew, or in the exercise of ordinary care, should have known, at the time the BioZorb device left their control.

75. Defendant knew and intended for the BioZorb Markers to be implanted in individuals, including Plaintiff.

76. Defendant expected that, and the BioZorb was indeed, sold and implanted in Plaintiff without a substantial change in condition.

77. Defendant sold the BioZorb in a defective condition making it unreasonably dangerous to users, including plaintiffs, as the BioZorb Markers contained inadequate warnings regarding their unreasonably dangerous condition when they left Defendant's control.

78. Defendant knew or should have known that BioZorb Markers presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

79. Plaintiff and Plaintiff's physician used the device in a normal, customary, intended, and foreseeable manner.

80. Defendant knew, or in the exercise of ordinary care, should have known that the BioZorb device could cause the injuries suffered by Plaintiff because Defendant was aware of post-marketing adverse event reports, otherwise known as Medical Device Reports ("MDRs"), that alleged the same or substantially similar injuries that were suffered by the Plaintiff in this lawsuit.

81. Defendant did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports.

82. Defendant was aware that BioZorb was designed in such a way that, following implant, it would perform in the recipient's body in a way that was not consistent with what Defendant stated in the product's instructions for use, and in a way that posed an unreasonably dangerous risk profile for patients.

83. The BioZorb device was not accompanied by proper warnings and instructions to the Plaintiff, physicians, hospitals, or the public regarding potential adverse side effects associated with the implantation of the device and the comparative severity and duration of such adverse side effects.

84. Specifically, the BioZorb's IFU (Instructions for Use) failed to include warnings that the BioZorb device may take several years to (and in some cases, may never) dissolve in the breast and need to be surgically removed. The warnings also failed to include information that a radiologist might need to use a higher energy electron therapy which can cause scarring on the breast.

85. The IFU also failed to adequately warn that the BioZorb is associated with chronic and/or serious adverse effects, including chronic and/or severe pain, infection, rash, device migration, device erosion, seromas, chronic discomfort, feeling of a lump in the breast (lack of resorbed device), and other complications related to lack of absorption of the device in the breast.

86. The IFU also failed to warn that the aforementioned adverse effects pose a significant risk of subsequent surgical treatment to remove the device and/or otherwise pose a risk of clinically significant sequelae including mass formation, infectious buildup, scarring, fat necrosis, adverse tissue reaction, and extrusion of the device from breast skin and tissue.

87. The above clinically significant issues and their association with the BioZorb device were known or knowable by the Defendant at the time the device was implanted into Plaintiff, which necessitated warnings, but Defendant failed to place such warnings in the IFU.

88. Had Plaintiff been warned of the aforementioned serious adverse effects, she would not have chosen to receive the BioZorb device and would have worked in conjunction with her implanting physician to receive an alternative treatment and/or device.

89. Defendant also marketed BioZorb in a manner beyond its indications for use, for example, to fill space in breast tissue and/or improve cosmetic outcomes after procedures, and participated in other "off label" promotional activities.

90. Defendant's sales representatives used "off label" promotional activities while also with failing to disclose to physicians the risks of BioZorb, which caused physicians, including Plaintiff's physician, to recommend to Plaintiff the BioZorb device while also holding an incomplete or otherwise inaccurate perception of its risk/benefit analysis.

91. Had Defendant disclosed the true risks of the BioZorb device to Plaintiff's physician, then this would have altered Plaintiff's implanting physician's risk/benefit analysis and would have caused Plaintiff's implanting physician to recommend an alternative treatment and/or device and/or would have caused Plaintiff to elect an alternative device.

92. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

93. Hologic is strictly liable for failing to adequately warn of the risks and risk profile of the BioZorb Marker.

94. WHEREFORE, the Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

95. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as is fully set forth herein.

96. At all relevant times, Defendant, directly or indirectly, designed, researched, developed, inspected, tested, assembled, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers.

97. Defendant designed, researched, developed, inspected, tested, assembled, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb with an implicit warranty that the BioZorb was fit for the ordinary purpose for which it was used, and, in Plaintiff's case, the use in which the BioZorb was warrantied was to be used as a radiation marker following breast cancer lumpectomy.

98. Defendant impliedly warranted to prospective purchasers and users, including Plaintiff, that the BioZorb device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

99. The product was expected to and did reach Plaintiff without substantial change in the condition which it was sold.

100. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiff, when they left Defendant's control.

101. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

102. Plaintiff and Plaintiff's physician used the device in a normal, customary, intended, and foreseeable manner.

103. Plaintiff reasonably relied upon the skill and judgement of Defendant as to whether the BioZorb device was of merchantable quality and safe and fit for its intended use.

104. Upon information and belief, and contrary to such implied warranties, the BioZorb device was not of merchantable quality or safe and fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

105. Further, Restatement (Second) of Torts Section 402A, comment "k", does not bar the Plaintiff's breach of implied warranty claim based on the Defendant's presumed position that the medical device at issue was unavoidably unsafe.

106. Defendant marketed BioZorb to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

107. Hologic breached the implied warranty of merchantability in connection with the sale and distribution of recalled BioZorb Markers. They were not in the conditions as represented or manufactured in accordance with specifications, in violation of state law and parallel federal law, for example 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.5, 21 C.F.R. § 820.3(y), 21 C.F.R.§ 820.70(a), (c), (e); 21 U.S.C. § 351. At the point of sale, the implants were not of merchantable quality, safe and fit for their intended use, in violation of applicable state law(s).

108. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

109. WHEREFORE, Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IV: STRICT LIABILITY – MANUFACTURING DEFECT

110. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as is fully set forth herein.

111. At all relevant times, Defendant, directly or indirectly, designed, researched, developed, inspected, tested, assembled, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers.

112. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

113. The BioZorb Markers were expected to and did reach the Plaintiffs without substantial change in the condition in which they were sold.

114. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

115. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

116. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

117. The manufacturing defects resulted from Defendant's action and/or inaction.

118. Plaintiffs were harmed because of the manufacturing defects.

119. The FDA found that a fall 2024 inspection "revealed that [BioZorb Markers] are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or

installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

120. Hologic is strictly liable for the defective manufacture of its BioZorb Marker pursuant to applicable state law(s).

121. WHEREFORE, Plaintiffs demand judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT V: NEGLIGENCE

122. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

123. At all times material hereto, Defendant, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted, advertised, sold and/or distributed into the stream of commerce the BioZorb device including the one implanted in Plaintiff.

124. Under federal and state law and regulation, Defendant was under a continuing duty to test and monitor the BioZorb device as well as their component parts, design, and manufacturing processes after premarket approval. The duties included establishing and validating its quality control systems and product suppliers, testing the device design, and investigating and reporting to the FDA any complaints about the device's performance and any malfunctions of which Defendant became aware and that are or may be attributable to the BioZorb device. See 21 C.F.R. Part 803; 21 C.F.R. Part 814; 21 C.F.R. Part 820; 21 U.S.C. §§ 351(h), 360i.

125. Defendant was negligent in designing, manufacturing, researching, developing, preparing, processing, packaging, promoting, marketing, labeling, supplying, inspecting, testing,

distributing, and selling the BioZorb by failing to use reasonable care in fulfilling their duty to avoid foreseeable dangers.

126. Defendant was negligent in failing to comply with federal and state law, and failing to use reasonable care in fulfilling their duty to inform users of dangerous risks, including risks posed by the device's negligent design. As a result of the foregoing conduct, Plaintiff's physicians, and hospitals were sold defective medical devices without knowing the true risk-benefit ration of the BioZorb.

127. Defendant knew or should have known that the risk of the BioZorb was different than what was in the IFU and communicated to patients, physicians, and hospitals.

128. Defendant knew or should have known that the BioZorb's benefits differed from what was marketed, promoted, advertised, and communicated to patients, physicians, hospitals, and the general public.

129. Defendant knew or should have known that the FDA did not clear the BioZorb marker to fill space in the breast tissue, improve cosmetic outcomes after procedures, or provide radiotherapy guidance.

130. Despite this knowledge, Defendant marketed the BioZorb to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

131. It was readily foreseeable to Defendant that Plaintiff and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and failure to report material information regarding the device's risks and claimed benefits. Defendant knew that Plaintiff and her physician and hospitals would use the medical device for its intended purpose, that their intended use would pose a substantial health risk to Plaintiff, and that Plaintiff, and the medical

community would rely on Defendant's representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant the BioZorb.

132. Under the same or similar circumstances, a reasonable manufacturer would have warned through an appropriate channel and medium of communication of the danger and reported the risks of BioZorb to patients, physicians, and hospitals.

133. Had Defendant adequately tested BioZorb, evidence regarding the device's risks, the rate of occurrence, and the extent of harm regarding each risk would have been found and could have been communicated to patients, physicians, and hospitals.

134. Had Defendant employed safety monitoring and pharmacovigilance measures for BioZorb, it could have mitigated or eliminated the risks posed by the BioZorb.

135. Had Defendant timely reported the known risks associated with the BioZorb to patients, physicians, and hospitals and allowed them to make informed decisions about using an alternative product that did not present the same risks, or foregoing the use of any marker, Plaintiff would not have been implanted with BioZorb.

136. Defendant knew that BioZorb's design was defective yet failed to take reasonable measures to mitigate or eliminate the risks posed by the defective design.

137. As a direct and proximate result of Defendant's actions and omissions, Plaintiff suffered injuries, including but not limited to physical pain, infection, subsequent surgeries, and emotional injuries.

138. As a result of the above negligence, Plaintiff suffered pain, medical expenses, emotional distress, and other economic and non-economic damages.

139. WHEREFORE, Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF AS TO ALL COUNTS

WHEREFORE, Plaintiff respectfully prays for judgment against the Defendant as follows:

a. Judgment in favor of Plaintiff and against Defendant, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including, but not limited to, medical expenses, loss of earnings, pain and suffering, mental anguish, and emotional distress, in amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre- and Post-judgment interest as provided by law; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury as to all issues herein.

Dated: March 11, 2025

/s/ Michael Appel

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